Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

# General

## Guideline Title

Best practice in outpatient hysteroscopy.

## Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG), British Society for Gynecological Endoscopy. Best practice in outpatient hysteroscopy. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Mar. 22 p. (Green-top guideline; no. 59). [86 references]

## Guideline Status

This is the current release of the guideline.

# Regulatory Alert

## FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

# Recommendations

## Major Recommendations

*In addition to these evidence-based recommendations, the guideline developer also identifies points of best clinical practice in the original guideline document.*

Classification of evidence levels (1++ to 4) and grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

Service Provision

*What Is the Ideal Setting for Performing Hysteroscopy?*

A - All gynaecology units should provide a dedicated outpatient hysteroscopy service to aid management of women with abnormal uterine bleeding. There are clinical and economic benefits associated with this type of service.

Analgesia

*Do Analgesics Given Before Diagnostic Hysteroscopy Reduce the Pain Felt by Women during the Procedure?*

B - Routine use of opiate analgesia before outpatient hysteroscopy should be avoided as it may cause adverse effects.

B - Women without contraindications should be advised to consider taking standard doses of non-steroidal anti-inflammatory agents (NSAIDs) around 1 hour before their scheduled outpatient hysteroscopy appointment with the aim of reducing pain in the immediate postoperative period.

Cervical Preparation

*Does Cervical Preparation Reduce Uterine Trauma, Failure to Access the Uterine Cavity or Pain Associated with Outpatient Hysteroscopy?*

A - Routine cervical preparation before outpatient hysteroscopy should not be used in the absence of any evidence of benefit in terms of reduction of pain, rates of failure or uterine trauma.

Type of Hysteroscope

*What Size and Angle of Hysteroscope Should Be Used in the Outpatient Setting?*

A - Miniature hysteroscopes (2.7 mm with a 3–3.5 mm sheath) should be used for diagnostic outpatient hysteroscopy as they significantly reduce the discomfort experienced by the woman.

*Should Rigid or Flexible Hysteroscopes Be Used Routinely in the Outpatient Setting?*

B - Flexible hysteroscopes are associated with less pain during outpatient hysteroscopy compared with rigid hysteroscopes. However, rigid hysteroscopes may provide better images, fewer failed procedures, quicker examination time and reduced cost. Thus, there is insufficient evidence to recommend preferential use of rigid or flexible hysteroscopes for diagnostic outpatient procedures. Choice of hysteroscope should be left to the discretion of the operator.

Operative outpatient hysteroscopy using miniature mechanical and electrosurgical equipment is becoming more established. These technologies generally require the use of rigid hysteroscopies. Units offering both hysteroscopic diagnosis and treatment in the outpatient setting should consider the versatility of respective hysteroscopes and relative resource implications when planning the composition of endoscopic equipment.

Distension Medium

*Which Uterine Distension Medium Should Be Used During Outpatient Hysteroscopy?*

A - For routine outpatient hysteroscopy, the choice of distension medium between carbon dioxide and normal saline should be left to the discretion of the operator as neither is superior in reducing pain, although uterine distension with normal saline appears to reduce the incidence of vasovagal episodes.

A - Uterine distension with normal saline allows improved image quality and allows outpatient diagnostic hysteroscopy to be completed more quickly compared with carbon dioxide.

Local Anaesthesia and Cervical Dilatation

*Should Routine Dilatation of the Cervical Canal Be Used Before Insertion of the Hysteroscope in an Outpatient Setting?*

C - Blind cervical dilatation to facilitate insertion of the miniature outpatient hysteroscope is unnecessary in the majority of procedures. Routine cervical dilatation is associated with pain, vasovagal reactions and uterine trauma and should be avoided.

*Should Topical Local Anaesthetic Be Administered before Outpatient Hysteroscopy?*

A - Instillation of local anaesthetic into the cervical canal does not reduce pain during diagnostic outpatient hysteroscopy but may reduce the incidence of vasovagal reactions.

A - Topical application of local anaesthetic to the ectocervix should be considered where application of a cervical tenaculum is necessary.

*Should Injectable Local Anaesthetic Be Administered to the Cervix and/or Paracervix before Outpatient Hysteroscopy?*

A - Application of local anaesthetic into or around the cervix is associated with a reduction of the pain experienced during outpatient diagnostic hysteroscopy. However, it is unclear how clinically significant this reduction in pain is. Consideration should be given to the routine administration of intracervical or paracervical local anaesthetic, particularly in postmenopausal women.

A - Routine administration of intracervical or paracervical local anaesthetic is not indicated to reduce the incidence of vasovagal reactions.

Conscious Sedation

*Should Conscious Sedation Be Used to Reduce Pain Associated with Outpatient Hysteroscopic Procedures?*

A - Conscious sedation should not be routinely used in outpatient hysteroscopic procedures as it confers no advantage in terms of pain control and the woman's satisfaction over local anaesthesia.

Vaginoscopy

*Does a Vaginoscopic Approach to Outpatient Hysteroscopy Reduce Pain and Increase the Feasibility of the Procedure?*

A - Vaginoscopy reduces pain during diagnostic rigid outpatient hysteroscopy.

Definitions:

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Gynaecologic conditions requiring outpatient hysteroscopy, including abnormal uterine bleeding or reproductive problems

## Guideline Category

Diagnosis

Management

## Clinical Specialty

Obstetrics and Gynecology

Surgery

## Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To provide clinicians with up-to-date, evidence-based information regarding outpatient hysteroscopy, with particular reference to minimising pain and optimising the woman's experience

## Target Population

Women undergoing outpatient hysteroscopy

## Interventions and Practices Considered

1. Use of a dedicated outpatient hysteroscopy service
2. Avoidance of opiates
3. Use of nonsteroidal anti-inflammatory drugs (NSAIDs) for analgesia
4. Use of miniature hysteroscopes
5. Choice of rigid or flexible hysteroscope

6. Uterine distension with normal saline (versus carbon dioxide)
7. Avoidance of routine cervical dilatation
8. Use of topical local anesthetic when necessary
9. Use of vaginoscopic approach

Note: The following were considered but not recommended: routine cervical preparation and routine use of conscious sedation.

### Major Outcomes Considered

- Procedural pain
- Feasibility of hysteroscopy procedures (e.g., failure rates)
- Image quality
- Time to perform procedure
- Adverse effects and complications of procedures

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Four databases were systematically searched: MEDLINE (from 1950 to September 2008), EMBASE (from 1980 to September 2008), CINAHL (from 1981 to September 2008) and the Cochrane library. No restrictions were placed on the searches in an attempt to reduce selection bias. The databases were searched using the relevant MeSH terms and keywords. The main keywords used were 'hysteroscopy and vaginoscopy', which were used with combinations of the following words depending upon the area of hysteroscopy being examined: 'anaesthesia', 'analgesia', 'distension media', 'flexible', 'rigid', 'cervical preparation', 'conscious sedation', 'prostaglandins' and 'laminaria'. The results of the searches were systematically reviewed.

### Number of Source Documents

Not stated

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship

is causal

2– Case–control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

## Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

Systematic reviews of the literature were conducted, with meta-analyses where possible, to assess pain and feasibility of outpatient hysteroscopy.

Reviewing and Grading of Evidence

Once the evidence has been collated for each clinical question it needs to be appraised and reviewed (refer to section 3 in "Development of RCOG Green-top guidelines: producing a clinical practice guideline" for information on the formulation of the clinical questions; see the "Availability of Companion Documents" field). For each question, the study type with least chance of bias should be used. If available, randomised controlled trials (RCTs) of suitable size and quality should be used in preference to observational data. This may vary depending on the outcome being examined.

The level of evidence and the grade of the recommendations used in this guideline originate from the guidance by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group, which incorporates formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base. The methods used to appraise individual study types are available from the SIGN Web site (www.sign.ac.uk/methodology/checklists.html ) An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (see the "Rating Scheme for the Strength of the Evidence" field). Where evidence is felt to warrant 'down-grading', for whatever reason, the rationale must be stated. Evidence judged to be of poor quality can be excluded. Any study with a high chance of bias (either 1– or 2–) will be excluded from the guideline and recommendations will not be based on this evidence. This prevents recommendations being based on poor-quality RCTs when higher-quality observational evidence is available.

## Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

## Description of Methods Used to Formulate the Recommendations

Guideline Development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high-quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy with another. This will therefore introduce the need for consensus.

Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guidelines are drafted by nominated developers, in contrast to other guideline groups such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network

(SIGN), who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based 'good practice points', the Guidelines Committee (GC) will employ an informal consensus approach through group discussion. In line with current methodologies, the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described, but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigor of the process but prevent undue delays in development.

## Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

## Cost Analysis

One randomised controlled trial reported more rapid mobilisation postoperatively (0 minutes [range 0–5] versus 105 minutes [range 80–120], P <0.001) and quicker recovery to preoperative levels (2 days [range 1–2.7] versus 3 days [range 2–4], P <0.05) favouring diagnostic outpatient hysteroscopy compared with traditional day-case hysteroscopy under general anaesthesia. The same study demonstrated high and equivalent levels of women's satisfaction with outpatient hysteroscopy in conscious women compared with daycase procedures under general anaesthesia. There were also economic benefits for women, the health service and society at large. Compared with day-case procedures under general anaesthesia, women undergoing outpatient hysteroscopy required significantly less time off work compared with the day-case group (0.8 days versus 3.3 days, P <0.001) and experienced reduced loss of income and reduced travel costs. Costs per woman to the National Health Service were estimated to be substantially less for outpatient procedures.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Following discussion in the Guidelines Committee (GC), each Green-top guideline is formally peer reviewed. At the same time, the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

All comments will be collated by the RCOG and tabulated for consideration by the guideline leads. Each comment will require discussion. Where comments are rejected then justification will need to be made. Following this review, the document will be updated and the GC will then review the revised draft and the table of comments.

Once the GC signs-off on the guideline, it is submitted to the Standards Board for approval before final publication.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

One study demonstrated high and equivalent levels of women's satisfaction with outpatient hysteroscopy in conscious women compared with daycase procedures under general anaesthesia. There were also economic benefits for women, the health service and society at large. Compared with day-case procedures under general anaesthesia, women undergoing outpatient hysteroscopy required significantly less time off work compared with the day-case group (0.8 days versus 3.3 days, P <0.001) and experienced reduced loss of income and reduced travel costs. Costs per woman to the National Health Service were estimated to be substantially less for outpatient procedures.

## Potential Harms

- Adverse effects of analgesic medications
- Complications (e.g., infection, vasovagal reactions, uterine trauma) of diagnostic and operative outpatient hysteroscopy

# Contraindications

## Contraindications

Prostaglandins are associated with gastrointestinal adverse effects and are contraindicated in severe uncontrolled asthma, chronic adrenal failure, acute porphyria, renal or hepatic impairment and breastfeeding.

# Qualifying Statements

## Qualifying Statements

- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.
- The Royal College of Obstetricians and Gynaecologists (RCOG) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available. This means that RCOG guidelines are unlike protocols or guidelines issued by employers, not being intended to be prescriptive directions defining a single

course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

- The British Society for Gynaecological Endoscopy (BSGE) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available. This means that BSGE guidelines are unlike protocols or guidelines issued by employers, not being intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

## Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

## IOM Domain

Effectiveness

Patient-centeredness

Safety

# Identifying Information and Availability

## Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG), British Society for Gynecological Endoscopy. Best practice in outpatient hysteroscopy. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Mar. 22 p. (Green-top guideline; no. 59). [86 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2011 Mar

## Guideline Developer(s)

British Society for Gynecological Endoscopy - Medical Specialty Society

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

## Source(s) of Funding

Royal College of Obstetricians and Gynaecologists

## Guideline Committee

Guidelines Committee

## Composition of Group That Authored the Guideline

*Authors*: Mr TJ Clark MRCOG, Birmingham; Dr NAM Cooper, Birmingham; Mr C Kremer FRCOG, Wakefield

*Peer Reviewers*: Mr PM Flynn MRCOG, Swansea; Dr MW Rodger FRCOG, Glasgow

*Guidelines Committee Lead Reviewers*: Mrs CE Overton FRCOG, Bristol; Dr J Shillito MRCOG, Leeds

## Financial Disclosures/Conflicts of Interest

Conflicts of interest: none declared.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .

## Availability of Companion Documents

The following are available:

- Development of RCOG Green-top guidelines: policies and processes. Clinical Governance Advice No 1a. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 6 p. Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site .
- Development of RCOG Green-top guidelines: producing a scope. Clinical Governance Advice No 1b. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 4 p. Electronic copies: Available from the RCOG Web site .

- Development of RCOG Green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 13 p. Electronic copies: Available from the RCOG Web site .
- Development of RCOG Green-top guidelines: consensus methods for adaptation of Green-top guidelines. Clinical Governance Advice No 1d. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Feb. 9 p. Electronic copies: Available from the RCOG Web site .

In addition, suggested audit topics are available in section 12 of the original guideline document .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on January 26, 2012. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

## Copyright Statement



# Disclaimer

## NGC Disclaimer